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EE/CA and RI/FS Support Sampling Plan

Sauget Area 1

Sauget and Cahokia, Illinois

Volume 4

Data Validation Plan

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Submitted By:

Solutia Inc.

ENVIRONMENTAL STANDARDS

Setting the Standards for Innovative Environmental Solutions

DATA VALIDATION PLAN

FOR THE SAUGET AREA 1 EE/CA and RI/FS

SAUGET, ILLINOIS

REVISION 1

April 1999

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Prepared for: Solutia

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1.0 INTRODUCTION

1.1 Project Description

The objective of the EE/CA and FI/FS support sampling is to further determine the extent of contamination at the Site beyond that already defined by previous site investigations. A brief summary of the Site location, general Site physiography, hydrology, and geology is included in the EE/CA and RI/FS Support Sampling Plan. A description of the data already available and data collected as part of this investigation will be included in the final EE/CA and RIU/FS report.

1.2 Data Validation

The analytical results generated for samples collected during this project will be the basis for any remedial action that takes place in the future. Data validation, in general terms, is a process that can determine if the analysis that has been performed conforms to specifications. Data validation also determines if the results are fit for use.

Data validation, in specific terms, is a complicated process whereby all of the hard copy instrument printouts (e.g., PCB chromatograms) associated with the samples are carefully examined. In order to demonstrate if the results from these samples are quantitatively and qualitatively reliable, the data must satisfy the following data quality indicators:

- Accuracy - A measure of how close a result is to the true value (i.e., analyzing a performance evaluation sample)
- Precision - A measure of the reproducibility of the measurements under a given set of circumstances (i.e., analyzing the same sample twice and comparing results).
- Representativeness - A measure of how a single (small) sample is indicative of a much larger sample (i.e., Will a sample collected at the top of a tank give the same results as one collected at the bottom?).
- Completeness - A measure of the amount of valid data obtained from the measurement system compared to the amount that is needed (i.e., If one is analyzing a sample for ten very similar compounds and the analysis for two of these compounds is valid, is there enough information to fulfill the objective?).
- Comparability - A measure of the confidence with which one data set can be described as similar to another. (i.e., If one uses pH paper, does that pH number compare well with the number obtained by the laboratory using a pH meter?).

A complete description of Environmental Standards' data validation procedures is described in Section 2.1.1 of this data validation plan.

2.0 SCOPE-OF-WORK

2.1 Quality Assurance Overview

Environmental Standards has the resources, qualifications and experience to become part of the project team in support of Solutia in this very important project without joint-venture subcontractors and without having to hire new personnel specifically for this project.

2.1.1 Data Validation

Environmental Standards has numerous volumes of internally developed data validation and report writing SOPs. Data Validation SOPs necessary for this project are presented in Appendix A. The Scope-of-Work outlined in the Support Sampling Plan, which will involve the validation of data generated during the investigation and remediation (when necessary), is consistent with the experience and capabilities of Environmental Standards.

According to the Support Sampling Plan, the analyses for this project will be performed in accordance with SW-846 analytical methods. This item brings up an issue which should be noted prior to the start-up of the project. The current EPA guidelines for data validation are directly applicable to the Superfund (CLP) analyses and do not necessarily apply to SW-846 analyses in many circumstances. For example, the current data validation guidelines for the pesticide/PCB analysis covers areas such as dual column results comparisons, Florisil cartridge checks, and resolution check standards which are not required by Method 8081A and might not be performed by the laboratory. In addition, there are no EPA guidelines for the validation of data for the herbicide analysis by GC. Accordingly, it is not always appropriate to rigorously apply the EPA CLP guidelines when validating data from SW-846 analyses. Environmental Standards recognizes the importance of this issue, and has addressed these items in our corporate SOPs.

A final note is that the performance of the data validation will be based on the USEPA Data Validation Functional Guidelines, 1994.

2.1.1.1 Data Validation Details

For data validation, a report will be prepared for each data package that provides a detailed assessment of data review activities and results. In addition, the pertinent information will be summarized in a transmittal letter signed by the Environmental Standards' chemist and senior chemist that have prepared/reviewed the report. The general format of an Environmental Standards' quality assurance review (data validation report) is presented on Table 1.

One original of each 10-15 page (typically) narrative report (including qualified spreadsheet summary data tables, the completed assessment checklists, the telephone record logs, and a transmittal letter) will be issued to Solutia for each data package received. The data package will be archived by

Environmental Standards once validation has been completed.

For standard turn-around time, Environmental Standards will provide complete validation reports to Solutia within 28 calendar days of Environmental Standards' receipt of each data package. If requested, faster turnaround times may be negotiated.

The data package deliverables will be "CLP like" or EPA Level IV (complete deliverables inclusive of raw data). Environmental Standards, Inc. assumes that project laboratory will provide a computer disk deliverable of the analytical results. This computer disk will present the data necessary for input into the project analytical database. Environmental Standards will record the appropriate qualifier codes and data validation findings on spreadsheets that are generated from the database. Environmental Standards will verify through this process that the laboratory electronic deliverables match the hardcopy analysis reports.

Data validation will be performed to include two areas: (1) compliance to the project-specific methods, the published methods and/or the requirements in the QAPP, and (2) usability based on the USEPA Data Validation Functional Guidelines. Compliance issues include not only checking if the laboratory performed the analysis properly but also checking for transcription errors and data package completeness.

2.1.1.2 Data Validation Report Format

A proposed format for the quality assurance reviews is presented in Table 1. The reports will be prepared by Sample Delivery Group (SDG) for ease of associating samples to reports. Based on the quality assurance review, specific codes will be placed next to results on the analytical data summaries (and/or updated directly onto the database - see Section 2.1.4) which can, at a glance, provide an indication of the quantitative and qualitative reliability of each result. The definitions of these qualifier codes (viz., glossary) will be provided with the report. The validated data summaries will be provided with the quality assurance reviews (validation reports). The narrative portion of the quality assurance review will be prepared using Microsoft® Word.

2.1.1.3 Data Package Deliverables (Hardcopy and Electronic)

The Environmental Standards' QA Chemist assigned the data package for validation will perform an initial completeness check of the data to make sure all of the required items are present in the data package. If not, the laboratory will be contacted by Environmental Standards' Data Validation Task Manager and requested to provide the missing information. (Solutia will be notified of the communication).

Electronic deliverables (analytical results on disk or data file transfer from the database over phone lines) will be printed out to verify that all necessary information is present and the results will be verified against those reported on the analytical summary forms (Form I's). Minor (transcription)

TABLE 1

FORMAT OF ENVIRONMENTAL STANDARDS' DATA VALIDATION REPORT

TRANSMITTAL PAGE

COVER PAGE

TABLE OF CONTENTS

INTRODUCTION AND SAMPLE LISTING

SECTION 1

1. Introduction

The introduction section will briefly state the number of samples analyzed, the laboratory(ies) that analyzed them, the parameters analyzed and the methods used.

2. Laboratory Compliance

This section of the draft report will specify any correctable and/or noncorrectable deficiencies that were identified relative to the organic, inorganic, radiological and wet chemistry requirements. Appropriate SW-846, or project citations will be provided for each item listed. This section will also specify all discrepancies between the reported data and the raw data. The final report will provide a description of the laboratory's corrective actions with regard to deficient items addressed in the draft report.

3. Data Qualifiers

This section will present qualifiers that should be considered in order for the data to best be utilized including a detailed assessment of the degree to which the data have been compromised by any deviation from protocol (i.e., lack of analytical control, QC failure, etc.). For every statement made in this section, there is a subsequent finding that justifies the qualifying statement. These qualifiers/findings are presented as bulleted items in order of importance relative to their impact on the data set. The data qualifiers will be presented in three subsections: organic data, inorganic data, and radiological/wet chemistry data. Within each subsection, the qualifiers will be presented by fraction.

SECTION 2

This section will include the qualified data tables, including a glossary defining the qualifier codes. These qualified data tables will be presented in the order of organics, inorganics and wet chemistry parameters.

SECTION 3

The organic data validation report is fully supported by a documentation appendix and completed validation checklist. For every qualifier made in the report, there is a photocopied page of laboratory data that is used in support of the reviewer's comments. All QC summary forms, as well as the reviewer's worksheets, are presented in the support documentation.

SECTION 4

The inorganic data validation report is also fully supported by a documentation appendix and completed validation checklist in the same format as the organic data. All QC summary forms, as well as the reviewer's worksheets, are presented in the support documentation.

SECTION 5

The wet chemistry data validation report is also fully supported by a documentation appendix and completed validation checklist in the same format as the organic data. All QC summary forms, as well as the reviewer's worksheets, are presented in the support documentation.

SECTION 6

This section of the quality assurance review will contain the laboratory case narratives and the field and laboratory Chain-of-Custody Records.

errors will be corrected by Environmental Standards. However, major problems noted with the data disk or data file will necessitate contacting the laboratory. Solutia will be notified of this communication with the laboratory. The print-out of the results will be kept with the data package and the data disk will be stored at Environmental Standards until the problem is resolved.

2.1.1.4 Data Package Receipt

Data packages arriving at Environmental Standards are received at the front desk and manually logged onto a receipt logbook by the Environmental Standards' Data Clerk. In addition, pertinent information (SDG number, fractions, number of samples and turn-around time) is entered on a project tracking board and the Data Validation Task Manager is informed of the arriving data package. The package is date stamped and a photocopy of the transmittal letter is filed in the project folder. A notation indicating the presence or absence of a data disk is made on the cover page for the data package. The data package is then relinquished to the Data Validation Task Manager for assignment a QA Chemist.

2.1.1.5 Data Validation Assignments

Weekly meetings are held for Environmental Standards' chemistry staff to discuss project issues and work in-house. At this time the data packages for the project will be distributed to the staff chemists along with project summaries stating important information such as applicable regulatory requirements, project-specific requirements, turn-around times and laboratory problems noted in previous data packages. Distribution of work is based on the available QA chemists and their areas of expertise. Daily work assignment sheets are utilized by each Data Validation Task Manager. In addition, a large common board is used to show on which projects individual chemists are currently working. This board is updated on a daily basis by each Environmental Standards' QA Chemist. If necessary, a chemist can check the board and inform all chemists working on a specific project (via inter-office E-mail) of an important issue/problem that has been observed in a data package. Each Data Validation Task Manager checks on a daily basis the progress of the staff chemists to ensure that the turn-around times are met for each and every data package.

2.1.1.6 Level of Review

The data validation is performed by reviewing the full CLP data package inclusive of all raw data. This level of validation is what Environmental Standards is best known for. Compliance issues as well as data usability are addressed in the quality assurance review. EVERY positive field sample result is recalculated from the instrument responses to the final (reported) result. Every noncompliance issue stated in the report is fully substantiated in the Support Documentation section of the report. Based on the data validation performed, the QA chemist modifies/qualifies the data summary table (and/or the database) of the reported laboratory results.

Environmental Standards has several electronic tools to assist in automating the validation of the data

These include Microsoft® Excel macros which calculate and display various quality control measures such as field duplicate/triplicate precision and technical holding times. In addition, Environmental Standards uses a Microsoft® Excel macro/database to compare relative peak height/area ratios for the identification and quantitation of positive results for PCB Aroclors.

2.1.1.7 Senior Technical Review

After the Environmental Standards' QA chemist has thoroughly reviewed the data package, a report is generated and sent through word processing (via internal network access) and technical editing. The QA chemist also prepares the Support Documentation section of the report and provides all materials (report, support documentation, and data package) to a Senior QA chemist for review. The Senior QA Chemist is responsible for ensuring that all items mentioned in the report are correct, clear, concise and well-documented. The Senior QA Chemist also checks that the data qualifier codes which appear on the data summary tables are appropriate and correct and that they are consistent with the findings in the report. As a final check, the results reported on the data tables are checked against the analytical summary forms; any differences between the two sets of results must be explained in the report and fully documented in the support documentation. The Program Manager **reads** and signs every report issued by Environmental Standards.

2.1.1.8 Turn-Around Time

Environmental Standards will provide one original of the data validation reports to Solutia within 28 calendar days (standard turn-around) of the receipt of each complete data package at Environmental Standards. The one exception to the specified 28-calendar-day turn-around time is that if the data package is incomplete and the laboratory must be contacted to provide missing data, the turn-around time will be extended by the number of days that the laboratory takes to provide the missing information to Environmental Standards.

2.1.1.9 Reporting and Data Archive

After word processing, technical editing and senior review, the quality assurance report and data summary tables are finalized by sending the report through the system once again (QA Chemist check, Senior QA Chemist review, word processing and technical editing) to assure that the report is correct and complete. The final report and tables are printed out and organized in binders with the support documentation. The original report will be sent to Solutia. The raw data and a second copy of the report are archived at Environmental Standards in a labeled box. Tracking of the location of all reports is performed with a database which lists reports by report number, archive box number, date issued and SDG. The database is kept in a limited access area of Environmental Standards

2.1.1.10 Complete Validation Report

For the purposes of this proposal, certain assumptions would be made concerning the final production of the validation reports. These assumptions include:

- Environmental Standards will be provided a laboratory disk deliverable and/or will have access to the data on the database which will be in a format in which MicroSoft® Excel data summary spreadsheets can be generated with minimal reformatting.

- A comprehensive evaluation of all raw data that is provided in the appropriate deliverable will be evaluated in detail including a rigorous evaluation of the chromatography for PCB data (as opposed to a percentage of the data "spot-checked").

- Validation will utilize Environmental Standards' internally developed proprietary automated software tools (e.g., evaluation of PCB data, holding times, etc.

- Validation will develop/follow Environmental Standards' internal SOPs for the evaluation/validation of data (SOPs are presented in Appendix A).

- A comprehensive 10-15 page quality assurance review (validation report) will be prepared for EACH data package validated.

- One original and one copy of each quality assurance review and an updated disk (and/or database update) will be issued via US Mail to Solutia. During urgent turn-around time situations, reports will either be electronically transmitted or Faxed.

2.1.2 Real-Time Laboratory QC Corrective Action

Often, project teams involved in a project such as this one are not informed about laboratory QC problems until the data packages are delivered from the laboratory, 30-60 days after samples are collected. As such, Environmental Standards recommends that the laboratories participating in this project be required to contact the project team immediately (by phone and fax) upon the discovery of any QC issue that may result in even the qualification of a data point. After Environmental Standards is informed of the QC issue, Environmental Standards will contact Solutia and recommend the course of action that will minimize the impact on the data quality. Similarly, if a decision is made to resample the sampling point and the problem is communicated quickly, potential expenses resulting from the sampling contractor remobilizing will be minimized.

3.0 PROJECT STAFF AND ORGANIZATION

Environmental Standards has organized an experienced professional staff to perform data validation for this project. The members of the Environmental Standards project team presented below are uniquely qualified to perform the required QA functions. Additionally, Environmental Standards' large chemistry staff provides ample capacity to complete high-volume data validation.

3.1 Project Staff, Responsibilities, and Qualifications

Environmental Standards' project staff members and their responsibilities are presented below. The experience and qualifications of each Environmental Standards chemistry staff member that will be available to participate on this project are presented in the Professional Profiles included in Appendix B.

3.1.1 Program Manager

Ms. Kathleen A. Blaine will serve as Environmental Standards' Program Manager. As Environmental Standards has placed a high priority on this project, Ms. Blaine will serve as the key administrative and technical contact, thus providing Solutia with direct access to an officer of Environmental Standards. Dr. Jill B. Henes will be the designated secondary contact (also a company officer). Ms. Blaine will be responsible for coordinating the various work elements, scheduling the various tasks, maintaining budget control, and reviewing all validation reports, and correspondence prior to their release to Solutia. Ms. Blaine will also track the technical efforts and ensure that sufficient staff and resources are available to complete the required tasks, and will perform budget and schedule oversight consistent with Environmental Standards' commitment to Solutia. A complete summary of Ms. Blaine's experience and credentials is presented in Appendix B of this proposal.

3.1.2 Data Validation Task Manager

Dr. Jill B. Henes will serve as the Data Validation Task Manager for this project. Dr. Henes' responsibilities will include tracking the analytical data deliverable receipt schedules to allow proper allocation of internal staff resources to this project. This will require routine communication and coordination with laboratory management personnel. Dr. Henes will be responsible for matching the laboratory data deliverables (summary package, reduced-CLP or full CLP) with the project validation requirements and assigning staff to perform the validation efforts. She will track the progress of the various validation efforts to ensure compliance with delivery schedules to Solutia. She will further be responsible for preparing budgets for the validation of project data, senior technical review of the data validation reports, assistance in the management of the data associated with the project, preparation/revisions to data validation SOPs (as required) for the review of data, and data validation training of staff quality assurance chemists relative to project specific requirements. A complete summary of Dr. Henes' experience and credentials is presented in Appendix B of this proposal.

3.1.3 Senior Quality Assurance Staff

Dr. Jill Henes, Ms. Meg Clark, Ms. Ruth Forman, Mr. Donald Lancaster, Ms. Kathy Blaine, and Mr. Stephen Zeiner are the Environmental Standards Senior Quality Assurance Staff that will be assigned to participate in data validation tasks of this project as necessary. Under direction of the Program and Task Managers the responsibilities of the Senior Quality Assurance Chemists will be to track, assign, and provide technical oversight of individual Sample Delivery Groups (SDGs) of analytical data requiring validation. Further, the Senior Quality Assurance Staff will be responsible for technical review of quality assurance reports prior to their distribution to the Program Manager for final review. Complete summaries of the Senior Quality Assurance Staff is presented in Appendix B of this proposal.

3.1.4 Quality Assurance Chemists

Quality Assurance Chemists will be assigned to the project as necessary to conduct the data validation tasks. Their responsibilities will include performance of data verification, compliance screening and/or validation; preparation of support documentation; and preparation of draft data review reports for internal senior review.

3.1.5 Administrative/Support Staff

Environmental Standards' support staff is structured into work groups identified as Production, Word Processing, Technical Editing, and Accounting. The responsibilities of Production and Word Processing for the project will be to coordinate report preparation and production to meet project schedules. All correspondence and reports produced by Environmental Standards are reviewed for grammatical errors and edited by a staff technical editor. Accounting support for production of project-specific budget or management summaries will be internally provided as necessary.

3.2 Environmental Standards' Approach to Managing Variable Work Loads

Environmental Standards has several in-house procedures to manage work loads and variable project schedules. First, communication with clients is of primary importance. The various Environmental Standards Managers' maintain routine contact with their clients to determine schedule changes and to determine project priorities. Task Managers meet on a weekly basis with the Program Manager to discuss project schedules, to evaluate current and projected work load, and to determine project priorities.

Environmental Standards Data Validation Task Managers track data validation work loads by using a Project Tracking Form, which contains the date on which a data package was received by Environmental Standards, the laboratory project number, the analyses performed, the number of

samples in the data package, the date on which the data package was assigned to QA, a notation specifying whether the data tables have been prepared, the date on which the draft and final report is due, and the date on which the report was sent. Additionally, each Senior QA Chemist tracks similar information for each chemist assigned to his or her work group.

The above information is updated on a daily basis and submitted to the Program Manager for review in order to determine the available resources. This information is also used in the weekly scheduling of meetings discussed above. Environmental Standards is well suited to be part of the project team and has a significant number of trained, experienced staff members to complete work of significant magnitude on schedule.

The Program Manager will conduct routine scheduling meetings with the various task managers to review project schedules and commitments. The Program Manager will be responsible for coordinating the work orders to prevent work load capacity problems. Conflicts with project schedules are expected to be nonexistent or minimal because of Environmental Standards' ample resources.